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Monitoring Programs Office  
8609 Sudley Rd., Ste. 206  
Manassas, VA 20110

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TO: See Distribution List

FROM: Martha Lamont, Director  
Monitoring Programs Office

SUBJECT: Microbiological Data Program Plan, January through June 2003

This Program Plan serves as the current Statement of Work for the period January through June 2003 for each State participating in the Microbiological Data Program (MDP). This document also stipulates work assignments for the Federal facility participating in MDP.

## **I. ADMINISTRATIVE UPDATES**

Program participants are reminded to keep MDP management informed of any critical equipment purchases, staffing issues, or expected increases in rent (e.g., due to laboratory or office renovation/relocation). This information is required under the terms of the MDP Cooperative Agreements (Section II, Responsibilities) between USDA and participating States.

### **A. Personnel**

Robert Whiddon has left the USDA Monitoring Program Office (MPO); he has accepted a position with the Department of Defense in the Washington, DC, area. Until his position is filled, Terry Councell will assume his MDP duties. Feel free to also contact Therese Murtagh regarding MDP issues and Patricia Moe or Sharon Williams for sampling concerns.

### **B. Financial/Cooperative Agreements**

The Fiscal Year 2003 (FY03) budget has not been approved yet, and a Continuing Resolution is providing funding in the interim. All MDP FY03 Cooperative Agreements will be issued once a budget is passed.

### C. MDP Program Meetings

An MDP public meeting was held at the Hilton Garden Inn, 815-14th Street, N.W., Washington, D.C., Nov. 20, 2002. At the meeting, MDP program activities to date were discussed and comments were solicited on the future direction of MDP.

The MDP Advisory Committee has been meeting monthly by teleconference; the next call will occur in mid-December (the actual date has yet to be determined). At that time the need for an MDP Technical Meeting will be discussed.

#### Technical Committee

Grace Hall, the MDP Technical Advisory Committee Chair, is currently developing the *Salmonella* BAX protocol. When finalized, MDP laboratories in California, Florida, Michigan, New York, North Carolina and Ohio, as well as the Minnesota Department of Agriculture laboratory will evaluate the BAX-PCR equipment in a side-by-side comparison with cultural methods.

#### Quality Assurance Overview

The MDP QA program covers all aspects of data gathering – from sample collection to data reporting. QA protocols for sampling are designed to protect sample integrity from the time of collection to the time of delivery at the testing facilities. QA protocols for testing comprise all laboratory operations from the time of sample receipt to the time data are reported to MDP's central database which is located in Manassas, Virginia. MDP laboratories guarantee reported results by adherence to strict QA requirements. The QA program is comprised of five elements: 1) Standard Operating Procedures (SOPs); 2) On-Site Reviews; 3) Proficiency Testing; 4) Quality Control (QC) Procedures; and 5) Method Performance and Verification Procedures.

#### Standard Operating Procedures (SOPs)

SOP	Responsibility	Next Steps
<u>MDP-LABOP-01</u> Infrared (IR) Thermometer Use	Kurt Mangione New York	MPO to call Kurt.
<u>MDP-LABOP-02</u> Sample Wash Procedures	Cindy Koschmann Wisconsin	Final draft has been provided to TAC. Comments due by 11/20/2002.
<u>MDP-LABOP-03</u> Microbiological Media	Gary Husby Washington State	Timeframe for draft revision by 11/30/02.
<u>MDP-LABOP-04</u> Shipping Microbiological Cultures	MPO	Review in January 2003.

<b>SOP</b>	<b>Responsibility</b>	<b>Next Steps</b>
<u>MDP-LABOP-05</u> Sample Receipt & Wash Procedure for Celery	Cindy Koschmann Wisconsin	Combined with LABOP-02.
<u>MDP-LABOP-06</u> Sample Receipt & Elution Procedure for Cantaloupe	Cindy Koschmann Wisconsin	Combined with LABOP-02.
<u>MDP-MTH-01</u> <i>Escherichia coli</i> MPN Method	Grace Hall Florida	Completed. 10/14/2002 revision on MDP web.
<u>MDP-MTH-02</u> <i>Salmonella</i> VIDAS Method	Fran Mohnke Michigan	Revised SOP to be distributed by MPO.

### **Proficiency Testing Program**

Proficiency test samples for MDP will be prepared by a private vendor according to program specifications. Quotes for this service have been received from Rtech and Silliker and are under review. The anticipated schedule is to send proficiency samples to laboratories every four months beginning in 2003. Scheduling will be determined in consultation with the laboratories.

### **D. Electronic Transfer of Data**

**Interim RDE System in Use:** All MDP laboratory facilities are using the MDP Remote Data Entry (RDE) software to perform data entry and/or generate transmit files for sampling, analysis, and quality assurance data. The MDP data is transmitted electronically to the MDP Staff Office using Internet e-mail facilities. The RDE software is an interim system developed in MS-Access that will be used until the reengineered joint MDP/PDP RDE software is implemented.

**RDE Reengineering Project:** Client Network Services, Inc. (CNSI) completed the development phase for the RDE reengineering project in October 2002. The RDE system was reengineered in order to ensure compatibility with new operating systems, to include provisions for shared resources with the Pesticide Data Program (PDP), and to employ new technology for capturing and transferring electronic data. The reengineered RDE system is a centralized system, where all RDE database files and support software will reside in Washington, D.C. and laboratory users will require only an Internet web browser on the front-end. A 20-day pilot ran from October 28, 2002 to November 22, 2002 which allowed MPO and laboratory users to test the RDE system in a real-time environment. A stand-alone SIF data entry system for laptop/desktop computers and for PDAs (Pocket PCs) was developed to allow the capture of SIF data electronically by sample collectors. The SIF data entry system can also be used by laboratories to perform data entry of paper SIF information off-line and then export it for import into the central RDE system. The reengineered RDE system is expected to become operational in December 2002. The reengineered RDE system should be used to enter data for all samples collected after January 1, 2003.

## **II. PROGRAM SAMPLING AND TESTING UPDATES**

Due to the ban FDA has placed on importing cantaloupe from Mexico earlier this month, some of our samplers are having difficulty finding this commodity. After the sample collector has taken appropriate measures to acquire the commodity (in accordance with MDP SOP No: SAMP PROC-1; checking primary, alternate and proxy sites), submit the SIF with the information noted so there is a record for the program files.

### **A. Sampling Changes and Rotations:** See the attached 2003 Shipping Charts.

**Sampling Deletions:** None

**Sampling Additions:** None

**Sampling Continuations:** Celery, leaf lettuce, romaine lettuce, tomatoes, and cantaloupe will continue.

### **B. Testing**

#### **Shipping Samples for Further Testing**

Shipment of samples to reference labs will continue unchanged for the next quarter. That is, samples testing positive for *E. coli* are shipped simultaneously to the ARS laboratory and to the laboratory at Pennsylvania State University (PSU). Samples testing positive for *Salmonella* are shipped simultaneously to the ARS laboratory and to the AMS National Science Laboratory in Gastonia, North Carolina.

#### **Microorganisms**

MDP laboratories will continue to test samples for *E. coli* (quantitative testing) and for *Salmonella* (presence or absence). Testing for *Shigella* will begin later in 2003, after a method has been developed in cooperation with FDA and validated in each laboratory.

**Commodity Deletions:** None

#### **Development of Testing Procedures for *Shigella***

USDA and FDA/CFSAN will work cooperatively on method development for *Shigella* testing using the BAX-PCR. MDP laboratories will be given progress updates during monthly teleconferences. MDP laboratories may also be asked to participate in method development. When the method is finalized, MDP laboratories in California, Florida, North Carolina, and Ohio, the Minnesota Department of Agriculture, FDA, and Canadian government laboratories will all participate in a validation study. Any testing of *Shigella* will occur after validation studies are completed for *Salmonella* BAX-PCR.

Attachments

## **DISTRIBUTION LIST:**

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